10-18-07

AF/IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Patton et al. Application No: 10/612,376 Confirmation No: 3703 Filed: July 1, 2003 Title: METHODS AND COMPOSITIONS FOR THE PULMONARY DELIVERY OF INSULIN	Group No: 1615 Examiner: Kishore, Gollamudi S. Attorney Docket No: NK.0005.15 Tuesday, October 16, 2007 San Francisco, CA 94107

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

VIA: Express Mail

☒ **Appeal Brief (Original)**
☒ **Transmittal of Appeal Brief**

Extension of Time

☐ Applicant petitions for an extension of time under 37 C.F.R. 1.136

Extension (Months)	Extension Fee	
	Large Entity	Small Entity
☐ One Month	$120.00	$60.00
☐ Two Months	$450.00	$225.00
☐Three Months	$1,020.00	$510.00

Total $ 0.00

☐ Applicant believes that no extension of term is required. However, this conditional petition is being made in case applicant has inadvertently overlooked the need for a petition for extension of time.

Fees for Extra Claims

	Claims remaining after amendment	Highest number previously paid for	Number Extra	Rate		Additional Fee
				Large Entity	Small Entity	
Total Claims	18	18	0	$50.00	$25.00	$0.00
Independent Claims	4	4	0	$200.00	$100.00	$0.00
Multiple Dependent Claims			0	$360.00	$180.00	$0.00
Supplemental Information Disclosure Statement						
					Total	**$0.00**

Fee Payment

Extension Fees	$0.00
Fees for Extra Claims	$0.00
Fee for Brief in Support of Appeal	$510.00
Total	**$510.00**

Fee Deficiency

☒ If any additional extension and/or fee is required, please charge Deposit Account No. 10-0258.
and/or
☒ If any additional fee for claims is required, please charge Deposit Account No. 10-0258.

☒ Attached is check no. 2759 in the sum of $510.00.
☐ Please charge Deposit Account No. _____ in the sum of $_____.

CERTIFICATE OF TRANSMISSION (37 C.F.R. § 1.8a):

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below or via facsimile to (571) 273-8300, or electronically filed on the date shown below:

By: _____ Date: October 16, 2007
Alison R. Parker

Please direct telephone calls to: Guy V. Tucker at (415) 538-1555

Please continue to send correspondence to:

Steve Helmer
Nektar Therapeutics
201 Industrial Road
San Carlos, CA 94070.

Respectfully Submitted,

By: _____ Date: October 16, 2007
Guy V. Tucker
Registration No. 45,302

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Patton et al. Application No.: 10/612,376 Confirmation No.: 3703 Filed: July 1, 2003 Title: METHODS AND COMPOSITIONS FOR THE PULMONARY DELIVERY OF INSULIN	Group Art Unit: 1615 Examiner: Kishore, Gollamudi S. Attorney Docket No: NK.0005.15 October 16, 2007 San Francisco, California

TRANSMITTAL OF APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Transmitted herewith, in triplicate, is the APPEAL BRIEF in this application, with respect to the Notice of Appeal filed on August 16, 2007.

This application is on behalf of a large entity.

The Appeal Brief is filed within two months of the Notice of Appeal. Thus, Applicant believes that no extension of time is required.

Certificate of Transmission

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, facsimile transmitted to the U.S. Patent and Trademark Office at (571) 273-8300, or electronically submitted, on the date shown below.

By: _____ Date: 10/16/07
Alison R. Parker

Applicant authorizes the Commissioner to charge the requisite fee of $510.00 for this Appeal Brief, as well as any other fees associated with this petition, to Deposit Account 10-0258.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

JANAH & ASSOCIATES
A PROFESSIONAL CORPORATION

Dated: October 16, 2007

By: _____
Guy V. Tucker
Reg. No. 45,302

Please direct all phone calls to:
Guy V. Tucker
(415) 538-1555

Please continue to send all correspondence to:

Steve Helmer
Nektar Therapeutics
201 Industrial Road
San Carlos, CA 94070

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Patton et al. Application No: 10/612,376 Confirmation No: 3703 Filed: July 1, 2003 Title: METHODS AND COMPOSITIONS FOR PULMONARY DELIVERY OF INSULIN	Group Art Unit: 1615 Examiner: Kishore, Gollamudi S. Attorney Docket No: NK.0005.15 October 16, 2007 San Francisco, California

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Examiner:

In response to the Examiner's Final Rejection of May 18, 2007, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby appeals to the Board of Patent Appeals and Interferences. Appellant requests the reversal of the Final Rejection. This Brief if being filed within two months of the filing of the Notice of Appeal.

Certificate of Transmission

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, facsimile transmitted to the U.S. Patent and Trademark Office at (571) 273-8300, or electronically submitted, on the date shown below.

By: _____ Date: 10/16/07
Alison R. Parker

TABLE OF CONTENTS

The Brief contains these items under the following headings, and in the order set forth below:

(1) *Real Party in Interest*

The real party in interest of the present application is Nektar Therapeutics (formerly Inhale Therapeutic Systems, Inc.), having a place of business at 201 Industrial Road; San Carlos, California 94070.

(2) *Related Appeals and Interferences*

Appellant, Appellant's legal representative, and assignee are aware of no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

(3) *Status of Claims*

Claims 26-43 are presently pending in the case. Claims 1-25 have been cancelled. Claims 31-34 and 39-43 have been finally rejected. Claims 26-30 and 35-38 have not been rejected, and Applicant presumes these claims are allowed. The rejection of each of claims 31-34 and 39-43 is hereby appealed.

(4) *Status of Amendments*

No amendments after Final Rejection have been filed. Accordingly, all amendments made during prosecution of the case have been entered.

(5) *Summary of the Claimed Subject Matter*

An insulin composition capable of being pulmonarily delivered is disclosed and discussed, for example on page 7 line 37 through page 9 line 2 of the specification. A version of the invention is set forth in claim 31 and described in the specification on, for example, page 11 lines 10-26. In this version, the insulin composition for pulmonary delivery comprises a dry powder of individual particles which include insulin present at

from 20% to 80% by weight in a pharmaceutical carrier material, such as a carbohydrate and/or an organic salt. Exemplary carrier materials are described on page 10 line 29 through page 11 line 9. The particles have an average size below 10 μm.

Another version of an insulin composition according to the invention is set forth in claim 39. According to this version, an insulin composition for pulmonary delivery comprises a dry powder of individual amorphous particles (described on page 9 line 20 through page 10 line 5) including both insulin and a pharmaceutical carrier (described, for example, on page 10 line 29 through page 11 line 9). The particles comprise from 20% to 80% insulin by weight (as described, for example, on page 11 lines 10-26), have an average particle size below 10 μm, and have a moisture content below 10% (as described on page 7 lines 28-31).

(6) *Grounds of Rejection to be Reviewed on Appeal*

Appellant requests review of the Examiner's following grounds of rejection:

Claims 31-34 and 39-43 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-58 of U.S. Patent Application No. 10/245,705 (hereinafter the '705 Application).

Claims 31-34 and 39-43 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-43 of U.S. Patent Application No. 10/245,706 (hereinafter the '706 Application).

Claims 31-34 and 39-43 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 13-16 of U.S. Patent 6,358,530 to Eljamal et al (hereinafter Eljamal et al).

(7) *Argument*

Appellant believes each of claims 31-34 and 39-43 are improperly rejected and are therefore allowable for the following reasons.

I. Independent claim 31 is allowable over the '705 Application

The Examiner's improper rejection of claim 31 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-58 (note that claims 30, 31, 34 and 50 have been cancelled) of the '705 Application should be reversed.

Nonstatutory double patenting is a judicially-created doctrine seeking to prevent the unjustified timewise extension of a patent. A nonstatutory obviousness-type double patenting rejection of claim 31 would be appropriate only if claim 31 is either anticipated by or would have been obvious over a claim in the '705 Application. Neither is the case here, as will be explained.

A. Claim 31 vis-à-vis independent claim 28 of the '705 Application

A side-by-side tabular comparison of Appellant's claim 31 and independent claim 28 and the claims depending therefrom in the '705 Application is provided:

Appellant's claim	'705 Application
31. An **insulin** composition for pulmonary delivery, said composition comprising a dry powder of individual particles which include **insulin present at from 20% to 80% by weight** in a pharmaceutical carrier material, wherein the particles have an	28. A therapeutic composition in dry powder form comprising a therapeutically effective amount of a pharmaceutical agent in combination with a pharmaceutical carrier, wherein said carrier is a bulking agent in the form of an

average size below 10 µm. (Emphasis added to highlight limitations not recited in compared claims).	amorphous powder, and wherein said composition is a powder suitable for administration by inhalation, wherein said powder comprises particles having a diameter less than about 10 µm and said pharmaceutical agent is available in said particles for rapid dissolution in fluid.
	29. The composition according to claim 28, wherein said powder comprises particles having a diameter of between 1 and 5 µm.
	43. The composition according to claim 28, wherein said carrier is a carbohydrate.
	44. The composition according to claim 28, wherein the pharmaceutically acceptable carrier is a monosaccharide selected from the group consisting of galactose, D-mannose, and sorbose.
	45. The composition according to claim 28, wherein the pharmaceutically acceptable carrier is a disaccharide selected from the group consisting of lactose and trehalose.
	46. The composition according to claim 28, wherein the pharmaceutically acceptable carrier is a disaccharide selected from the group consisting of raffinose, maltodextrins and dextran.
	47. The composition according to claim 28, wherein said carrier is an alditol selected from the group consisting of mannitol and xylitol.

	48. The composition according to claim 28, wherein the composition is spray dried.
	49. The composition according to claim 28, wherein the carrier is combined with the pharmaceutical agent prior to being spray-dried.

No claim in the claim set consisting of claims 28, 29 and 43-49 of the '705 Application anticipates Appellant's claim 31. As can be seen from the above table, Appellant's claim 31 recites features that are not present in a claim in the above claim set. For example, Appellant's claim 31 recites an "insulin composition" and further recites "insulin present at from 20% to 80% by weight in a pharmaceutical carrier material." Independent claim 28 and the claims depending therefrom in the '705 Application fail to recite at least these features and therefore fail to anticipate claim 31.

In addition, no claim in the claim set consisting of claims 28, 29 and 43-49 of the '705 Application renders Appellant's claim 31 unpatentable as being obvious. A double patenting rejection of the obviousness type when not based on an anticipation rationale is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. §103." *In re Braithwaite*, 379 F.2d 594. The obviousness or nonobviousness analysis therefore parallels the analysis of a 35 U.S.C. §103 obviousness determination. *In re Braat*, 937 F.2d 589; *In re Longi*, 759 F.2d 887.

Applying the 35 U.S.C. §103 analysis, Appellant's claim 31 is not rendered unpatentable by the invention defined in any of the claims in the claim set consisting of claims 28, 29 and 43-49 in the '705 Application. Claim 31 recites an insulin composition and further recites that the insulin is present at from 20% to 80% by weight in a pharmaceutical carrier material. These features are not present in the invention defined by claims 28, 29 and 43-49 of the '705 Application. Since these features are not present and since the Examiner has provided no basis for making a modification that

would result in the invention defined by Appellant's claim 31, there is no prima facie case established. Also, when considering whether the invention defined by a claim of an application is an obvious variation of a claim in a patent, the disclosure of the patent may not be used as prior art. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272. Thus, it follows that in determining whether Appellant's claim 31 would have been an obvious variation of the invention defined in the '705 Application, the disclosure of the '705 Application may not be used as prior art.

For at least these reasons, Appellant's claim 31 is not properly rejectable under obviousness-type double patenting as being unpatentable over the claim set consisting of claims 28, 29 and 43-49 of the '705 Application. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have modified the invention defined by claims 28, 29 and 43-49 of the '705 Application in a manner that would result in the invention of Appellant's claim 31, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Furthermore, Appellant has unexpectedly found that the invention as defined in Appellant's claim 31 provides for the pulmonary delivery of insulin in a way that can be an effective alternative to administration by subcutaneous injection, as discussed for example on page 4 lines 32-37 in the specification. Thus, Appellant's claim 31 is allowable over claims 28, 29, and 43-49 of the '705 Application.

B. Claim 31 vis-à-vis independent claim 32 of the '705 Application

A side-by-side tabular comparison of Appellant's claim 31 and independent claim 32 and the claims depending therefrom in the '705 Application is provided:

Appellant's claim	'705 Application
31. An **insulin** composition for pulmonary delivery, said composition comprising a	32. A therapeutic composition in dry powder form comprising a therapeutically

dry powder of individual particles which include **insulin present at from 20% to 80% by weight** in a pharmaceutical carrier material, wherein the particles have an average size below 10 μm. (Emphasis added to highlight limitations not recited in compared claims).	effective amount of a pharmaceutical agent in combination with a pharmaceutically acceptable carrier, wherein said carrier is a bulking agent in the form of an amorphous powder, said therapeutic composition is a powder suitable for administration by inhalation, the pharmaceutical agent is selected from the group consisting of insulin, interleukin-1 receptor, parathyroid hormone (PTH-34), alpha-1-antitrypsin, calcitonin, low molecular weight heparin, interferon and nucleic acids, and said powder comprises particles having a diameter less than about 10 μm and said pharmaceutical agent is available in said particles for rapid dissolution in fluid.
	51. The composition according to claim 32, wherein said powder comprises particles having a diameter of between 1 and 5 μm.
	52. The composition according to claim 32, wherein said carrier is a carbohydrate.
	53. The composition according to claim 32, wherein the pharmaceutically acceptable carrier is a monosaccharide selected from the group consisting of galactose, D-mannose, and sorbose.
	54. The composition according to claim 32, wherein the pharmaceutically acceptable carrier is a disaccharide selected from the

	group consisting of lactose and trehalose.
	55. The composition according to claim 32, wherein the pharmaceutically acceptable carrier is a disaccharide selected from the group consisting of raffinose, maltodextrins and dextran.
	56. The composition according to claim 32, wherein said carrier is an alditol selected from the group consisting of mannitol and xylitol.
	57. The composition according to claim 32, wherein the composition is spray dried.
	58. The composition according to claim 32, wherein the carrier is combined with the pharmaceutical agent prior to being spray-dried.

No claim in the claim set consisting of claims 32 and 51-58 of the '705 Application anticipates Appellant's claim 31. As can be seen from the above table, Appellant's claim 31 recites features that are not present in a claim in the claim set. For example, Appellant's claim 31 recites "insulin present at from 20% to 80% by weight in a pharmaceutical carrier material." Independent claim 32 and the claims depending therefrom in the '705 Application fail to recite at least this feature and therefore fail to anticipate claim 31.

In addition, no claim in the claim set consisting of claims 32 and 51-58 of the '705 Application renders Appellant's claim 31 unpatentable as being obvious. Claim 31 recites an insulin composition and further recites that the insulin is present at from 20% to 80% by weight in a pharmaceutical carrier material. First, claim 32 of the '705

Application recites a list of active ingredients of which insulin is but one of many possibilities. The Examiner has not established how it would have been obvious to select insulin from that list. Furthermore, even assuming it would have been obvious to select insulin the Examiner has provided no basis to support the contention that it would have been obvious to have insulin present at from 20% to 80% by weight in a pharmaceutical carrier material. Thus, there is no prima facie case of obviousness established by the Examiner.

For at least these reasons, Appellant's claim 31 is not properly rejectable under obviousness-type double patenting as being unpatentable over the claim set consisting of claims 32 and 53-58 of the '705 Application. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have modified the invention defined by claims 32 and 53-58 of the '705 Application in a manner that would result in the invention of Appellant's claim 31, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Furthermore, Appellant has unexpectedly found that the invention as defined in Appellant's claim 31 provides for the pulmonary delivery of insulin in a way that can be an effective alternative to administration by subcutaneous injection, as discussed, for example on page 4 lines 32-37 in the specification. Thus, Appellant's claim 31 is allowable over claims 32 and 53-58 of the '705 Application.

C. Claim 31 vis-à-vis independent claim 33 of the '705 Application

A side-by-side tabular comparison of Appellant's claim 31 and independent claim 33 and the claims depending therefrom in the '705 Application is provided:

Appellant's claim	'705 Application
31. An **insulin** composition for pulmonary delivery, said composition comprising a	33. A therapeutic composition in dry powder form comprising a therapeutically

dry powder of individual particles which include **insulin present at from 20% to 80% by weight** in a pharmaceutical carrier material, wherein the particles have an average size below 10 μm. (Emphasis added to highlight limitations not recited in compared claims).	effective amount of a pharmaceutical agent in combination with a pharmaceutically acceptable carrier, wherein said carrier is a bulking agent in the form of an amorphous powder, said therapeutic composition is a powder suitable for administration by inhalation, the pharmaceutical agent is selected from the group consisting of calcitonin, erythropoietin, Factor IX, granulocyte colony stimulating factor, granulocyte macrophage colony stimulating factor, growth hormone, heparin, insulin, interferon α, interferon β, interferon δ, interleukin-2, luteinizing hormone releasing hormone, somatostatin analog, vasopressin analog, amylin, ciliary neurotrophic factor, growth hormone releasing factor, insulin-like growth factor, insulinotropin, interleukin-1 receptor antagonist, interleukin-3, interleukin-4, interleukin-6, macrophage colony stimulating factor, nerve growth factor, parathyroid hormone, somatostatin analog, thymosin alpha 1, lib/IIIa inhibitor, α-1 antitrypsin, anti-RSV antibody, cystic fibrosis transmembrane regulator (CFTR) gene, bactericidal/permeability increasing protein, anti-CMVantibody, interleukin-1 receptor, pentamidine isethiouate,

	albuterol sulfate, metaproterenolsulfate, beclomethasone diprepionate, trimcinoline acetomide, budesonide acetonide, ipratroprium bromide, flunisolide, cromolyn sodium and ergotamine tartrate, and said powder comprises particles having a diameter less than about 10 μm and said pharmaceutical agent is available in said particles for rapid dissolution in fluid.
	35. The composition according to claim 33, wherein said powder comprises particles having a diameter of between 1 and 5 μm.
	36. The composition according to claim 33, wherein said carrier is a carbohydrate.
	37. The composition according to claim 33, wherein the pharmaceutically acceptable carrier is a monosaccharide selected from the group consisting of galactose, D-mannose, and sorbose.
	38. The composition according to claim 33, wherein the pharmaceutically acceptable carrier is a disaccharide selected from the group consisting of lactose and trehalose.
	39. The composition according to claim 33, wherein the pharmaceutically acceptable carrier is a disaccharide selected from the group consisting of raffinose, maltodextrins and dextran.
	40. The composition according to claim 33, wherein said carrier is an alditol selected

	from the group consisting of mannitol and xylitol.
	41. The composition according to claim 33, wherein the composition is spray dried.
	42. The composition according to claim 33, wherein the carrier is combined with the pharmaceutical agent prior to being spray-dried.

No claim in the claim set consisting of claims 33 and 35-42 of the '705 Application anticipates Appellant's claim 31. As can be seen from the above table, Appellant's claim 31 recites features that are not present in a claim in the above claim set. For example, Appellant's claim 31 recites "insulin present at from 20% to 80% by weight in a pharmaceutical carrier material." Independent claim 33 and the claims depending therefrom in the '705 Application fail to recite at least this feature and therefore fail to anticipate claim 31.

In addition, no claim in the claim set consisting of claims 33 and 35-42 of the '705 Application renders Appellant's claim 31 unpatentable as being obvious. Claim 31 recites an insulin composition and further recites that the insulin is present at from 20% to 80% by weight in a pharmaceutical carrier material. First, claim 33 of the '705 Application recites a list of active ingredients of which insulin is but one of many possibilities. The Examiner has not established how it would have been obvious to select insulin from that list. Furthermore, even assuming it would have been obvious to select insulin the Examiner has provided no basis to support the contention that it would have been obvious to have insulin present at from 20% to 80% by weight in a pharmaceutical carrier material. Thus, there is no prima facie case of obviousness established by the Examiner.

For at least these reasons, Appellant's claim 31 is not properly rejectable under obviousness-type double patenting as being unpatentable over the claim set consisting of claims 33 and 35-42 of the '705 Application. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have modified the invention defined by claims 33 and 35-42 of the '705 Application in a manner that would result in the invention of Appellant's claim 31, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Furthermore, Appellant has unexpectedly found that the invention as defined in Appellant's claim 31 provides for the pulmonary delivery of insulin in a way that can be an effective alternative to administration by subcutaneous injection, as discussed for example on page 4 lines 32-37 in the specification. Thus, Appellant's claim 31 is allowable over claims 33 and 35-42 of the '705 Application.

II. Independent claim 39 is allowable over the '705 Application

The Examiner's improper rejection of claim 39 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-58 (note that claims 30, 31, 34, and 50 have been cancelled) of the '705 Application should also be reversed.

Independent claim 39 is not anticipated by or rendered unpatentable as being an obvious variant of any of the claims in the '705 Application. Claim 39 is to an insulin composition for pulmonary delivery, said composition comprising: a dry powder of individual amorphous particles including both insulin and a pharmaceutical carrier, wherein the particles comprise from 20% to 80% insulin by weight, have an average particle size below 10 μm, and have a moisture content below 10%. The claim set consisting of claims 28, 29 and 43-49 of the '705 Application does not define an invention that is an insulin composition and does not define an invention wherein particles comprise from 20% to 80% insulin by weight. The claim set consisting of claims 32 and 51-58 and the claim set consisting of claim 33 and 35-42 does not clearly

define an invention that is an insulin composition and does not define an invention wherein particles comprise from 20% to 80% insulin by weight. In addition, the Examiner has not established a prima facie case of obviousness in that there has been no suggestion as to how one of ordinary skill in the art would have found it obvious to modify the invention defined in the '705 Application in a manner that would result in the invention of independent claim 39.

III. The dependent claims are also allowable over the '705 Application

Claims 32-34 depend from claim 31 and claims 40-43 depend from claim 39. Since the independent claims are not properly rejectable under the doctrine of obviousness-type double patenting, the claims depending therefrom are also not properly rejectable. Thus, Appellant requests reversal of the rejection of each of claims 31-34 and 39-43.

IV. The rejection based on the '706 Application should be withdrawn

The Examiner should withdraw the provisional rejection of claims 31-34 and 39-43 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-43 of the '706 Application.

Since the present case is otherwise in condition for allowance, the present case should be allowed to issue and the double patenting issue should be taken up in the pending '706 Application. The present claims are otherwise in condition for allowance for the reasons described herein. Accordingly, the present case should be allowed to issue. To require Appellant to file a terminal disclaimer in the present case would require speculation as to the claims that will eventually issue in the '706 Application. If it turns out that the claims resulting from the '706 Application are patentably distinct from the present claims, then Appellant would have been unduly and unfairly required to submit the disclaimer.

The Examiner's reliance on MPEP §800 (see Final Office Action page 3) is not proper. According to the Examiner, if the obviousness-type double patenting rejection is the only rejection remaining in a later-filed application, a terminal disclaimer must be required in the later-filed application. Be that as it may, that is not the situation in the present case. The present application and the '706 Application were both filed on the same day (i.e. they both have the same effective filing date). Thus, there is no timewise extension of the patent term with which to be concerned, and since there is no "later-filed application" the MPEP provisions relied on by the Examiner are of no moment.

For at least these reasons, the rejections of claims 31-34 and 39-43 based on the '706 Application should be withdrawn and/or reversed.

V. Independent claim 31 is allowable over the claims of Eljamal et al

The Examiner's improper rejection of claim 31 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 13-16 of Eljamal et al should be reversed.

The issuance of present claim 31 would not result in an unjustified extension of a patent term. The nonstatutory obviousness-type double patenting rejection is a judicially-created doctrine seeking to prevent the unjustified timewise extension of a patent. The present application has an effective filing date of March 7, 1994. Eljamal et al has an effective filing date of April 14, 1995 which is later than the effective filing date of the present application. Thus, a terminal disclaimer in the present case would not result in the prevention of an unjustified timewise extension of the Eljamal et al patent.

In addition, a nonstatutory obviousness-type double patenting rejection of claim 31 would not be appropriate if claim 31 is neither anticipated by, nor would have been obvious over, a claim in the later-filed Eljamal et al patent.

A side-by-side tabular comparison of Appellant's claim 31 and the claims in

Eljamal et al is provided:

Appellant's claim	Eljamal et al
31. An **insulin** composition for pulmonary delivery, said composition comprising a dry powder of individual particles which include **insulin present at from 20% to 80% by weight** in a pharmaceutical carrier material, wherein the particles have an average size below 10 μm. (Emphasis added to highlight limitations not recited in compared claims).	1. A spray-dried dispersible powdered composition suitable for inhalation by a human subject, comprising: (a) a therapeutically effective amount of an active agent suitable for treating a condition in said subject by inhalation; (b) a pharmaceutically acceptable excipient selected from the group consisting of carbohydrates and amino acids; and (c) a dispersibility-enhancing amount of a physiologically-acceptable, water-soluble polypeptide.
	2. The composition of claim 1 wherein the excipient is a carbohydrate.
	3. The composition of claim 2, wherein said carbohydrate is selected from the group consisting of monosaccharides, disaccharides, trisaccharides, and polysaccarides.
	4. The composition of claim 3, wherein said carbohydrate is a monosaccharide selected from the group consisting of dextrose, galactose, mannitol, D-mannose, sorbitol, and sorbose.
	5. The composition of claim 3, wherein said excipient is a disaccharide selected

	from the group consisting of lactose, maltose, sucrose, and trehalose.
	6. The composition of claim 1 wherein the excipient is an amino acid.
	7. The composition of claim 6 wherein the amino acid is a hydrophobic amino acid.
	8. The composition of claim 7 wherein the hydrophobic amino acid is selected from the group consisting of alanine, isoleucine, leucine, methionine, phenylalanine, proline, tryptophan, and valine.
	9. The composition of claim 6 wherein the amino acid is a polar amino acid.
	10. The composition of claim 9 wherein the amino acid is selected from the group consisting of arginine, histidine, lysine, cystine, glycine, glutamine, serine, threonine, tyrosine, aspartic acid and glutamic acid.
	11. The composition of claim 1 wherein the excipient is present in an amount of about 50% by weight to about 99.9% by weight.
	13. The composition of claim 1 comprising particles having a mass median diameter (MMD) of less than 10 microns.
	14. The composition of claim 13 comprising particles having a mass median diameter of less than 5 microns.
	15. The composition of claim 1 comprising particles having a mass median

	aerodynamic diameter (MMAD) of less than 5 microns.
	16. The composition of claim 1, wherein said active agent is selected from the group consisting of steroids, bronchdilators, mast cell inhibitors, antibiotics, polypeptides and nucleic acids.

No claim in Eljamal et al anticipates Appellant's claim 31. As can be seen from the above table, Appellant's claim 31 recites features that are not present in a claim in the above claim set. For example, Appellant's claim 31 recites an "insulin composition" and further recites "insulin present at from 20% to 80% by weight in a pharmaceutical carrier material." The claims of Eljamal et al fail to recite at least these features and therefore fail to anticipate claim 31.

In addition, no claim in Eljamal et al renders Appellant's claim 31 unpatentable as being obvious. Applying the 35 U.S.C. §103 style of analysis, Appellant's claim 31 is not rendered unpatentable by the invention defined in any of the claims in Eljamal et al. Claim 31 recites an insulin composition and further recites that the insulin is present at from 20% to 80% by weight in a pharmaceutical carrier material. These features are not present in the invention defined by the claims of Eljamal et al. Since these features are not present and since the Examiner has provided no basis for making a modification that would result in the invention defined by Appellant's claim 31, there is no prima facie case established.

The Examiner's contention in the Final Office Action (see page 4) that the Eljamal et al claims anticipate Appellant's claim 31 because insulin is a polypeptide is not with merit. A " a dispersibility-enhancing amount of a physiologically-acceptable, water-soluble polypeptide" as recited in Eljamal et al's claim 1 does not anticipate the "insulin composition" limitation in Appellants claim 31 and does not anticipate the "insulin

present at from 20% to 80% by weight in a pharmaceutical carrier material" limitation in Appellant's claim 31.

For at least these reasons, Appellant's claim 31 is not properly rejectable under obviousness-type double patenting as being unpatentable over the claims of Eljamal et al. The modification to the invention defined by the claims of Eljamal et al that would be necessary to arrive at the invention of Appellant's claim 31 is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have modified the invention defined by the claims of Eljamal et al in a manner that would result in the invention of Appellant's claim 31, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, Appellant's claim 31 is allowable over the claims of Eljamal et al.

VI. Independent claim 39 is also allowable over the claims of Eljamal et al

The Examiner's improper rejection of claim 39 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 13-16 of Eljamal et al should be reversed.

The issuance of present claim 39 would not result in an unjustified extension of a patent term. The nonstatutory obviousness-type double patenting rejection is a judicially-created doctrine seeking to prevent the unjustified timewise extension of a patent. The present application has an effective filing date of March 7, 1994. Eljamal et al has an effective filing date of April 14, 1995 which is later than the effective filing date of the present application. Thus, a terminal disclaimer in the present case would not result in the prevention of an unjustified timewise extension of the Eljamal et al patent.

In addition, a nonstatutory obviousness-type double patenting rejection of claim 39 would not be appropriate if claim 39 is neither anticipated by, nor would have been obvious over, a claim in the later-filed Eljamal et al patent.

A side-by-side tabular comparison of Appellant's claim 39 and the claims in Eljamal et al is provided:

Appellant's claim	Eljamal et al
39. An **insulin composition** for pulmonary delivery, said composition comprising: a dry powder of individual **amorphous particles** including both **insulin** and a pharmaceutical carrier, wherein the particles **comprise from 20% to 80% insulin by weight**, have an average particle size below 10 μm, and have a **moisture content below 10%**. (Emphasis added to highlight limitations not recited in compared claims).	1. A spray-dried dispersible powdered composition suitable for inhalation by a human subject, comprising: (a) a therapeutically effective amount of an active agent suitable for treating a condition in said subject by inhalation; (b) a pharmaceutically acceptable excipient selected from the group consisting of carbohydrates and amino acids; and (c) a dispersibility-enhancing amount of a physiologically-acceptable, water-soluble polypeptide.
	2. The composition of claim 1 wherein the excipient is a carbohydrate.
	3. The composition of claim 2, wherein said carbohydrate is selected from the group consisting of monosaccharides, disaccharides, trisaccharides, and polysaccarides.
	4. The composition of claim 3, wherein said carbohydrate is a monosaccharide selected from the group consisting of dextrose, galactose, mannitol, D-mannose, sorbitol, and sorbose.

	5. The composition of claim 3, wherein said excipient is a disaccharide selected from the group consisting of lactose, maltose, sucrose, and trehalose.
	6. The composition of claim 1 wherein the excipient is an amino acid.
	7. The composition of claim 6 wherein the amino acid is a hydrophobic amino acid.
	8. The composition of claim 7 wherein the hydrophobic amino acid is selected from the group consisting of alanine, isoleucine, leucine, methionine, phenylalanine, proline, tryptophan, and valine.
	9. The composition of claim 6 wherein the amino acid is a polar amino acid.
	10. The composition of claim 9 wherein the amino acid is selected from the group consisting of arginine, histidine, lysine, cystine, glycine, glutamine, serine, threonine, tyrosine, aspartic acid and glutamic acid.
	11. The composition of claim 1 wherein the excipient is present in an amount of about 50% by weight to about 99.9% by weight.
	13. The composition of claim 1 comprising particles having a mass median diameter (MMD) of less than 10 microns.
	14. The composition of claim 13 comprising particles having a mass median diameter of less than 5 microns.

	15. The composition of claim 1 comprising particles having a mass median aerodynamic diameter (MMAD) of less than 5 microns.
	16. The composition of claim 1, wherein said active agent is selected from the group consisting of steroids, bronchdilators, mast cell inhibitors, antibiotics, polypeptides and nucleic acids.

No claim in Eljamal et al anticipates Appellant's claim 39. As can be seen from the above table, Appellant's claim 39 recites features that are not present in a claim in the claim set. For example, Appellant's claim 39 recites an "insulin composition" and further recites "wherein the particles comprise from 20% to 80% insulin by weight." These features are not claimed by Eljamal et al. Furthermore, Appellant's claim 39 recites "a dry powder of individual amorphous particles" and "a moisture content below 10%." These features are also not claimed by Eljamal et al.

In addition, no claim in Eljamal et al renders Appellant's claim 39 unpatentable as being obvious. The insulin composition, the amount of insulin present, the amorphous particles, and the dryness of the particles are not defined by the claims of Eljamal et al. Since these features are not present and since the Examiner has provided no basis for making a modification that would result in the invention defined by Appellant's claim 31, there is no prima facie case of obviousness established.

For at least these reasons, Appellant's claim 39 is not properly rejectable under obviousness-type double patenting as being unpatentable over the claims of Eljamal et al. The modification to the invention defined by the claims of Eljamal et al that would be necessary to arrive at the invention of Appellant's claim 39 is not one that would have been well within the grasp of one of ordinary skill in the art at the time the

invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have modified the invention defined by the claims of Eljamal et al in a manner that would result in the invention of Appellant's claim 39, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, Appellant's claim 39 is allowable over the claims of Eljamal et al.

VII. The dependent claims are also allowable over Eljamal et al

Claims 32-34 depend from claim 31 and claims 40-43 depend from claim 39. Since the independent claims are not properly rejectable under the doctrine of obviousness-type double patenting based on Eljamal et al, the claims depending therefrom are also not properly rejectable. Thus, Appellant requests reversal of the rejection of each of claims 31-34 and 39-43.

VIII. Conclusion

Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

JANAH & ASSOCIATES

Dated: 16OCT2007

By: _____

Guy V. Tucker
Reg. No. 45,302
(415) 538-1555

Please send all correspondence to:
Steve Helmer
Nektar Therapeutics
201 Industrial Road
San Carlos, CA 94070

(8) Claims Appendix

31. An insulin composition for pulmonary delivery, said composition comprising a dry powder of individual particles which include insulin present at from 20% to 80% by weight in a pharmaceutical carrier material, wherein the particles have an average size below 10 μm.

32. An insulin composition as in claim 31, wherein the composition is substantially free from penetration enhancers.

33. An insulin composition as in claim 31, wherein the pharmaceutical carrier material comprises a carbohydrate selected from the group consisting of mannitol, raffinose, lactose, malto dextrin, and trehalose.

34. An insulin composition as in claim 31, wherein the pharmaceutical carrier material comprises an organic salt selected from the group consisting of sodium citrate, sodium gluconate, and sodium ascorbate.

39. An insulin composition for pulmonary delivery, said composition comprising:

a dry powder of individual amorphous particles including both insulin and a pharmaceutical carrier, wherein the particles comprise from 20% to 80% insulin by weight, have an average particle size below 10 μm, and have a moisture content below 10%.

40. An insulin composition as in claim 39, wherein the particles consist essentially of the insulin and the pharmaceutical carrier.

41. An insulin composition as in claim 39, wherein the composition is substantially free from penetration enhancers.

42. An insulin composition as in claim 39, wherein the pharmaceutical carrier material comprises a carbohydrate selected from the group consisting of mannitol, raffinose, lactose, malto dextrin, and trehalose.

43. An insulin composition as in claim 39, wherein the pharmaceutical carrier material comprises an organic salt selected from the group consisting of sodium citrate, sodium gluconate, and sodium ascorbate.

(9) Evidence Appendix

none

(10) Related Proceedings Appendix

none